

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Application for
Endarterectomy Surgical Instrument

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Endarterectomy Surgical Instrument

The present application claims priority from U.S. Provisional
5 Application, Serial No. 60/165,707, filed November 16, 1999, and incorporated
herein by reference.

Field of the Invention

The present invention pertains to surgical instruments and
10 procedures, and more particularly to the removal of plaque build-ups within
blood vessels.

Background Art

Excessive plaque build-up within arteries decreases the blood flow
15 capacity of the arteries and of the living tissue supplied by the arteries.
Normal blood flow may be restored by either removing the plaque build-up
or by bypassing the blocked section of the artery. In a bypass procedure, a
second blood vessel is attached to, and parallel to, the vessel to be bypassed
and provides a flow path around the blocked section of the artery. The
20 second blood vessel has one end attached upstream of the blocked section
and the second end attached downstream of the blocked section.
Alternatively, the blockage may be removed from the artery by opening the
artery along the blockage and removing the blockage. Both procedures
require incisions along the blockage and become extremely invasive for
25 extensive blockages that may run the length from the groin to the knee, for
example.

A less invasive procedure for removing plaque build-ups requires
only two incision points; one above the blockage and one below the blockage.
A catheter is inserted into the artery at the up-stream incision point and is
30 pushed toward the second incision point that is downstream from the
blockage. The catheter head is configured to either grab or loosen the plaque
build-up along the blockage. As the catheter is passed through the blockage,

the build-up is pushed ahead of the catheter and is removed at the second incision point. Although the catheter will remove sufficient blockage to restore normal flow, the procedure may not remove all the build-up.

Depending on the type of catheter head used in the procedure, there exists a risk that the catheter head may penetrate through the plaque build-up layer, the intima and media layers of the artery and damage the adventitia layer of the artery. In addition, the procedure does not remove the blockage from the side branches of the artery and may worsen the blockage of the side branches by a "snowplow" effect.

Instead of pushing a catheter through the blood flow channel of the artery, gas endarterectomy uses a gas to separate the media layer surrounding the blockage from the adventitia layer of the artery. Once separated from the adventitia layer of the artery, the blockage may be easily removed from the downstream incision point or from the initial incision point if the blockage is less than about an inch. The downstream incision point is still required because the intima and media layers of the artery attached to the blockage site must be separated from the intima and media layers of the non-blocked artery section. Although the gas endarterectomy procedure also requires two incisions, the procedure does not suffer from the "snowplow" effect of the catheter procedure and may also remove the side branch plugs along with the main blockage. In addition, all plaque is removed in a gas endarterectomy procedure because the underlying intima and media layers containing the plaque are removed.

In U.S. patent number 5,954,713 ('713) issued on September 21, 1999 to Newman, et. al., a gas endarterectomy procedure is described wherein only one incision point is required. The '713 patent describes a spatula head having an optical channel for illumination and viewing of the space in front of the spatula head, gas flow channels for the gas that separates the media layer from the adventitia layer, and liquid flow channels for clearing the optics and removing debris. In the procedure described in the '713 patent, after the spatula head is used to separate the blockage from the artery, the spatula head is removed from the artery and a surgical cutting instrument is

inserted into the artery and moved to the end of the blockage whereupon the surgical cutting instrument cuts the intima and media layers of the artery. The blockage is then removed from the artery by pulling the blockage through the incision using forceps or the surgical cutting instrument.

5 As described, however, the procedure described in the '713 patent requires two instruments: the spatula instrument and the cutting instrument. Furthermore, both instruments must be worked through the blockage. This increases the duration of the requisite operation and the risk of damage to the adventitia layer of the artery. It is thus preferable to have a single instrument
10 that both separates the media layer from the adventitia layer and then removes the blockage.

The media and intima layers are preferably cut at the point where the gas endarterectomy has separated the layers from the adventitia layer. Using prior art practice, damage to the adventitia may occur if the cut is made
15 beyond the separation point. If the cut is made behind the separation point, the separated media and intima layers will form a flap within the artery. In accordance with prior art practice, a stent is usually inserted to prevent formation of the flap. The stent covers the transition region between the section of the artery where the media and intima layers have been removed
20 with the blockage and the section of the artery where the media and intima layers are intact.

Summary of the Invention

It has been observed that the media and intima layer is fairly weak at
25 the transition between the plaque build-up and no-plaque build-up regions. Therefore, by grabbing the blockage and pulling, the blockage will tend to separate from the healthy media and intima layers at the transition without the use of a cutting tool. By eliminating the cutting tool, risk to the patient may be advantageously reduced, additionally, only the diseased portion of
30 the media and intima layers need be removed. Furthermore, in accordance with embodiments of the invention, the break occurs at the point where the healthy media and intima layers are separated, thereby producing a

smoother transition region.

In accordance with embodiments of the present invention, a separate surgical cutting instrument may be eliminated by adding a grabbing or grasping function to the spatula head of the endarterectomy surgical instrument provided in accordance with the present invention. The spatula head contains either hooks, barbs, or prongs that can be deployed by the operator. The hooks or barbs may be retracted after deployment. A gas channel is preferably incorporated into the shaft of the instrument, either as a separate channel or with an endoscope in an optical channel.

The endarterectomy surgical instrument provided in accordance with preferred embodiments of the present invention has a shaft with proximal and distal ends. A head, coupled to the distal end of the shaft, has an endoscope port and at least one fluid port, while a handle, coupled to the proximal end of the shaft, has a gas supply port in fluid communication with the at least one gas port on the head, a flow valve for metering flow of gas between the gas supply port and the at least one fluid port on the head, and a locking mechanism for retaining an endoscope.

In accordance with alternate embodiments of the invention, the endarterectomy surgical instrument may also have saline solution inlet coupled to the handle for coupling a flow of saline solution to the at least one fluid port on the head. Fluid connection of the handle to the head of the shaft may be provided through a first lumen, while an endoscope may provide optical coupling through a second lumen between the distal and proximal ends of the shaft. The first and second lumens may be separate or identical.

The instrument may also have a grasping device with both a retracted configuration and a deployed configuration, the grasping device extending away from the head in the deployed configuration. The grasping device may be a barb or a hook, and it may be controlled by a deployment control disposed on the handle of the instrument.

In accordance with a further embodiment of the invention, there is provided an endarterectomy surgical instrument that has a shaft with proximal and distal ends and a head coupled to the distal end of the shaft.

The head has an endoscope port and at least one fluid port. A handle, coupled to the proximal end of the shaft, has a fluid supply port in fluid communication with the at least one fluid port on the head and a locking mechanism for retaining an endoscope.

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Brief Description of the Drawings

FIG. 1a shows a perspective view of one embodiment of the present invention in the retracted configuration;

FIG. 1b shows a perspective view of the embodiment shown in FIG 1a in the deployed configuration;

FIG. 2a shows a front view of the head of the embodiment shown in FIG. 1a;

FIG. 2b shows a front view of the head of the embodiment shown in FIG. 1b;

FIG. 3a shows a front view of the head of the embodiment shown in FIG. 1a inside an artery;

FIG. 3b shows a front view of the head of the embodiment shown in FIG. 1b inside an artery;

FIG. 4a shows a perspective view of the head in another embodiment of the invention in the retracted configuration;

FIG. 4b shows a perspective view of the head of the embodiment shown in FIG 4a in the deployed configuration;

FIG. 5 is a perspective view of the head of another embodiment with one of the hooks not shown;

FIG. 6a shows a front view of the head inside an artery of the embodiment shown in FIG. 4a;

FIG. 6b shows a front view of the head inside an artery of the embodiment shown in FIG. 4b;

FIG. 6 shows a cut side view of the handle of the embodiment of Fig. 1a;

FIG. 7a shows a cut bottom view of the head of the embodiment shown

in FIG. 1a; and

FIG. 7b shows a cut bottom view of the head of the embodiment shown in FIG 1a in the deployed configuration;

FIG. 8 is a perspective view of the head of another embodiment with one of the hooks not shown; and

FIG. 9 shows a cut side view of the handle of the embodiment of Fig. 8.

Detailed Description of Specific Embodiments

FIG. 1a shows a perspective view of an embodiment of the present invention in the retracted configuration. The gas endarterectomy surgical instrument, generally designated by numeral **10** comprises a head **11**, connected to a shaft **12**, which in turn is connected to a handle **13**. The handle **13** houses a gas port **14** that connects to a gas supply, not shown. The gas flow delivered to the head **11** is controlled by a variable flow valve **15**. An endoscope latch **16** is provided on the handle **13** to secure an endoscope to the surgical instrument **10**. The handle also houses a deployment control that controls the deployment or retraction of a grasping device located in the head **11**. In the embodiment shown in FIG. 1a, the deployment control is a slide **17**. The handle **13** is connected to shaft **12** which is a flexible tube providing multiple lumens as now described.

In accordance with this embodiment of the invention, shaft **12** is sized to provide flow paths both for the gas from the gas supply and for saline solution to the head **11** while also accommodating the endoscope and a control wire, not shown. The control wire is attached to the slide **17** on the handle at one end and is attached to the grasping device located in the head **11** at the other end. The head **11** is attached to the end of the shaft **12** opposite the end attached to the handle **13**. The head **11** is provided with an opening that holds the end of the endoscope and also provides exit orifices for the gas and saline solution. The head **11** also contains a grasping device that may be deployed by the operation of the deployment control. FIG. 1b

shows the surgical instrument of FIG. 1a in the deployed configuration. In FIG. 1b, the slide 17 has been moved to the rear position, thereby deploying the grasping mechanism, which, in this embodiment of the invention, is a pair of barbs 18.

5 FIG. 2a shows a front view of head 11 in the retracted configuration of one embodiment of the invention. FIG. 2b shows a front view of head 11 in the deployed configuration of the embodiment shown in FIG. 2a. Head 11 has an outer side 21 that is shaped to approximate the inner wall of an artery. The inner side 22 of head 11 is generally flattened. The tip of head 11
10 contains an endoscope port 23 and a plurality of ports 24 for the delivery of gas and/or saline solution. The gas ports are in fluid communication with the gas flow path of the shaft 12 through internal channels within the head 11. The end of the endoscope is held by the head by sizing the diameter of the endoscope port 23 to the size of the endoscope. FIG. 2b shows the front
15 view of the head 11 in the deployed configuration. In the embodiment of the invention shown in FIG. 2b, a plurality of barbs or prongs 25 are deployed from the inner surface 22 and extend away and towards the rear of head 11.

 FIG. 3a shows a front view of head 11 of one embodiment of the invention placed in the artery of a patient. The head 11 of the surgical
20 instrument is pushed between the adventitia layer 31 of the artery and the media layer 32 of the artery with the outer side 21 of the head 11 against the adventitia layer 31 of the artery and the inner side 22 of the head 11 facing the media layer 32 of the artery. The media layer 32 encircles the intima layer, not shown, on which the plaque forms a build-up layer 33 that obstructs the
25 blood flow channel 34. Gas jets from the gas ports 24 separates the adventitia layer 31 from the media layer 32, creating an interstitial chamber 35 through which the head 11 can travel along the blockage caused by the plaque build-up layer 33. FIG. 3b shows the front view of the head 11 shown in FIG. 3a with the barbs 25 deployed. The barbs 25 are deployed away from the inner
30 surface 22 of the head 11 and extend into the media layer 32 and the build-up layer 33 of the obstruction. As the head 11 is pulled backward, the rear facing

barbs 25 securely grab the obstruction, thereby removing the obstruction as the head 11 is removed from the artery. The barbs 25 may also be retracted after deployment by operating the deployment control to retract the barbs 25 while slightly urging the head 11 forward.

5 FIG. 4a shows a perspective view of the head of another embodiment of the present invention. FIG. 4b shows a perspective view of the head of the embodiment of the invention shown in FIG. 4a with the grasping mechanism deployed. In this embodiment of the invention, the grasping mechanism comprise a plurality of hooks 43. Hooks 43 are positioned at the front of the
10 head 41 next to the endoscope 44. Hooks 43 are housed in channels 45 that terminate at the front of the head. The hooks 43 are attached to a control wire, not shown, that is passed through the shaft 42 and connected at the other end to the deployment control, not shown, on the handle.

FIG. 5a shows a front view of the embodiment shown in FIG. 4a in the
15 artery. FIG. 5b shows a front view of the embodiment shown in FIG. 4a in the artery of a patient in the deployed configuration. The head 51 is positioned between the adventitia layer 52 and the media layer 53 of the artery. Gas from gas ports 58 is used to open an interstitial space 56 between the adventitia layer 52 and the media layer 53 to allow the head 51 to travel
20 parallel to the build-up layer 54 and the obstructed blood flow channel 55. Each hook 43 is housed in a gas flow channel 58. Additional gas flow channels may be provided by side channels 57 on the endoscope port 59. In the deployed configuration, as shown in FIG. 5b, the each hook 43 extends forward of the head 51. As the head 51 is removed from the artery, each
25 hook 43 grabs onto the media layer 53 and build-up layer 54 thereby removing the obstruction as the head 51 is removed from the artery.

FIG. 6 is a side cut view showing the internal channels of the handle in one embodiment of the present invention. An external gas source is connected to the surgical instrument by a gas port 14 and supplies gas to the
30 head of the surgical instrument. In a preferred embodiment, the gas is CO₂. The gas flows through the inlet passageway 610 to a variable flow valve 15,

exiting through an outlet passageway 615. Outlet passageway 615 is connected to an endoscope passageway 616 which, in turn, is connected to the shaft 12 at the shaft end 617.

Variable flow valve 15 comprises a knob 620 attached to a control piston 621, the end of which may be displaced into or out of the outlet passageway 615. The inlet passageway 610 is isolated from the outlet passageway 615 by a first sealing ring 618. The inlet passageway 610 is maintained in fluid isolation with the environment by a second sealing ring 619. The first sealing ring 618 is held against the handle body 605 by the control piston 621. Control piston 621 has a notch 622 along the side of the piston 621. As control piston 621 is displaced into the outlet passageway 615 by pressing on the knob 620, the notch 622 is moved under the first sealing ring 618. Notch 622 relieves the pressure placed on the first sealing ring 618 by piston 621. The reduction of pressure placed on the first sealing ring 618 allows gas from the inlet passageway 610 to flow around the first sealing ring 618 to the outlet passageway 615. The profile of the notch 622 is shaped such that as the piston 621 is displaced further into the outlet passageway 615, more gas is allowed to flow into the outlet passageway 615 from the inlet passageway 610.

Outlet passageway 615 is in fluid communication with the endoscope passageway 616 thereby allowing gas from the gas supply to flow through shaft 12. An endoscope, not shown, may be placed in endoscope passageway 616 and through shaft 12. The endoscope is sized to provide sufficient gas flow between the endoscope and the inner surface of shaft 12 to separate the adventitia layer from the media layer of the artery. The endoscope is held in place by an endoscope locking mechanism 16. Endoscope locking mechanism 16 may be a latch having a latch pad 630 that holds the endoscope in place when endoscope latch 16 is in a closed position, or, alternatively, the locking mechanism may be a quarter turn lock. The endoscope is sealed by pressing the endoscope against a wiper seal 633 before locking the endoscope in place. The endoscope latch 16 may be released from the closed position to an open

position by a latch handle 632. The design of the latch handle 632 is well known to one of ordinary skill in the mechanical arts. The endoscope latch 16 is moved from a closed position to an open position by rotating the endoscope latch 16 about a pivot 631.

5 In one embodiment of the invention, the surgical instrument 10 may use either a disposable or reusable endoscope from a variety of manufacturers. For example, the INTRAMED® angioscope models 700070 (a 1.9 mm disposable), 702016 (1.9 mm diameter; reusable), or 702023 (2.4 mm diameter; reusable), all from Baxter International, Inc. may be used in the present invention. Model A5000 (1.7 mm diameter; disposable angioscope) or Model A5102 (1.7 mm diameter; reusable angioscope), both from Applied Medical Resources of Laguna Hills, CA, or instruments employing similar principles, may also be used in the present invention.

15 In another embodiment of the invention, surgical instrument 10 may be configured without an endoscope, allowing the physician to decide if an endoscope is necessary for the particular procedure. A plug may be used instead of an endoscope to reduce the cost of the procedure. The plug is configured to form a seal with the wiper seal 633 and to be held in place by the latch pad 630. In another embodiment, the plug may also comprise of a length of plastic or metallic material having substantially the same diameter and length of an endoscope in order to provide additional stiffness to the shaft 12.

FIG. 7a shows a cut bottom view of the head of the embodiment shown in FIG. 1a showing the internal passageways within the head. Head 11 is attached to shaft 12. A control wire 70 is disposed inside shaft 12 and terminates in the head 11 at the wire end 71. Wire end 71 connects the end of the control wire 70 to the end of at least one barb wire 72. The opposite end of the barb wire 72 is attached to the barb 25. Control wire 70, wire end 71, barb wire 72, and barb 25 are positioned in a channel 73 to allow for free movement of the wires 70, 72, wire end 71 and barb 25 within the head 11. The channel 73 is in fluid communication with the gas port 24 and endoscope port 23.

FIG. 7b shows a cut bottom view of the head of the embodiment shown in FIG 1a in the deployed configuration. Deployment of the barb 25 is accomplished by withdrawing control wire 70 from head 11. The withdrawal of control wire 70 cause wire end 71 and the barb wire 72 to move in a rearward direction away from the endoscope port 23 and toward the handle 13. The rearward movement of the barb wire 72 pushes barb 25 along channel 73 such that barb tip 75 and barb 25 extend substantially beyond the barb channel opening 74 in the head 11.

FIG. 8 shows a perspective view of head 80 of shaft 82, in accordance with other embodiments of the invention. Shaft 82 contains at least one lumen for the delivery of gas (typically carbon dioxide) and/or saline solution via one or more ports 84. Another lumen through shaft 82 allows an endoscope to emerge at endoscope port 86. Endoscope port 86 may be shaped, like the lumen through which the endoscope is threaded, with a notch (or 'sidechannel') 87 to provide for delivery of gas and/or saline solution through the endoscope lumen. Two retractable hooks 88 are shown, whereas a third retractable hook is preferably deployed through port 90 but has been omitted to allow clearer depiction of the central region of the head.

Saline solution is delivered for purposes of keeping the endoscope clear, and thus also the image as viewed by the surgeon. Saline solution is preferably delivered through a separate lumen rather than through an endoscope with its own working channel. A separate lumen is preferred because the working channel of an endoscope is difficult to sterilize, in that it is an internal space, and thus may require the additional expense of a disposable endoscope. An endoscope having a diameter of approximately 0.9 mm and lacking a working channel is preferably employed in this embodiment of the invention.

FIG. 9 is a side cut view showing the internal channels of handle 900 in the embodiment of the present invention depicted in FIG. 8. An external gas source is connected to the surgical instrument by a gas port 914 and supplies gas to the head of the surgical instrument. In a preferred embodiment, the

sized to provide sufficient gas flow between the endoscope and the inner surface of shaft 82 to separate the adventitia layer from the media layer of the artery. The endoscope is held in place by an endoscope locking mechanism

940
916 having a latch pad 930 that holds the endoscope in place when endoscope
5 locking mechanism 916 is in a closed position.

In an alternate embodiment of the invention, gas and saline solution may be conveyed through the same passageway 916 as contains the endoscope. In this case, a gas-tight seal 933 is preferably used.

Having thus described various illustrative embodiments of the present
10 invention, some of its advantages and optional features, it will be apparent that such embodiments are presented by way of example only and are not by way of limitation. Those skilled in the art could readily devise alternations and improvements on these embodiments, as well as additional
15 For example, although a control wire is used to deploy or retract the grasping device, a collar may be attached to the endoscope end that engages the grasping device. The grasping device may be deployed or retracted by unlocking the endoscope latch on the handle and moving the endoscope forward or backward in the shaft. Alternatively, head 11 may be employed in
20 the manner of a spatula. All such modifications are within the scope of the invention as claimed.